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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,078	07/25/2001	William F. Wade	PM	7302

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/720078	Applicant(s) W10E
	Examiner GAMBEL	Art Unit 1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 1-31

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☑ Claim(s) _____ are subject to restriction and/or election requirement. 1-31

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

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DETAILED ACTION

1. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

One of the special technical features of the instant application is a method of enhancing a humoral immun response to a target antigen with an antibody-antigen conjugate and an anti-CD40 antibody.

Puri (U.S. Patent No. 5,204,449) teaches antigen antibody conjugates for MHC Class I/II antigens to enhance their immunogenicity as well as to target said antigens to cells of the immune response (see entire document). Ledbetter et al. (U.S. Patent NO. 5,247,069) teach the use of the CD40-specific G28-5 antibody to enhance immune responses (see entire document, including column 17-20). The motivation to combine the prior art can arise from the expectation that the prior art elements will perform their expected function to achieve their expected results when combined for their common known purpose. Here, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine both antigen antibody conjugates for MHC Class I/II antigens and CD40-specific antibodies to target antigens to the appropriate cells of interest, including CD40-expressing antigen presenting cells, as well as to enhance the immunogenicity of said antigens.

Therefore the inventions of either the Groups I/II/below have not been found to have no special technical feature that defines the contribution over the prior art.

Accordingly, Groups I-XVI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Prior to setting forth the Groups below, the following is noted.

Given the opposite effects of enhancing and suppressing immune responses, claims 1-17 are split into different Groups accordingly.

In addition, it is pointed out that the claims are drawn to patentably distinct methods and products. The method and products rely upon antigens and antibodies which differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the various Groups are set forth below, irrespective of the format of the claims.

Furthermore, the claims are drawn to anti-dendritic cell antigen antibody, anti-follicular cell antigen antibody and anti-Fc molecule antibody. If applicant elects one of these Groups, then this elected Group may be subject to further division, given that each dendritic cell antigen, follicular cell antigen and Fc

I. Claims 1, 4-17, drawn to methods of enhancing a humoral response or CD4 Th1 immune response with a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-MHC class II antibody.

II. Claims 1, 2, 5-17, drawn to methods of enhancing a humoral response or CD4 Th1 immune response with a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-MHC Class I antibody.

III. Claims 1, 2, 5-17, drawn to methods of enhancing a humoral response or CD4 Th1 immune response with a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-dendritic cell antibody.

IV. Claims 1, 2, 5-17, drawn to methods of enhancing a humoral response or CD4 Th1 immune response with a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-follicular cell antigen antibody.

V. Claims 1, ,2, 5-17, drawn to methods of enhancing a humoral response or CD4 Th1 immune response with a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-Fc antibody.

VI. Claims 1-3, 5-17, drawn to methods of suppressing a humoral response or CD4 Th1 immune response with a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-MHC class II antibody.

VII. Claims 1-2, 5-17 drawn to methods of suppressing a humoral response or CD4 Th1 immune response with a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-MHC Class I antibody.

VIII. Claims 1-2, 5-17, drawn to methods of suppressing a humoral response or CD4 Th1 immune response with a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-dendritic cell antibody.

IX. Claims 1-2, 5-17, drawn to methods of suppressing a humoral response or CD4 Th1 immune response with a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-follicular cell antigen antibody.

X. Claims 1-2, 5-17, drawn to methods of suppressing a humoral response or CD4 Th1 immune response with a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-Fc antibody.

XI. Claims 18-19, 21-30, drawn to compositions comprising a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-B7 antibody and kits thereof.

XII. Claims 18-30, drawn to compositions comprising a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-MHC class II antibody and kits thereof.

XIII. Claims 18-19, 21-30, drawn to compositions comprising a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-MHC Class I antibody and kits thereof.

XIV. Claims 18-19, 21-30, drawn to compositions comprising a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-dendritic cell antibody and kits thereof.

XV. Claims 18-19, 21-30, drawn to compositions comprising a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-follicular cell antigen antibody and kits thereof.

XVI. Claims 18-19, 21-30, drawn to compositions comprising a conjugate comprising an antibody-antigen conjugate and an anti-CD40 antibody, wherein the antibody is an anti-Fc antibody and kits thereof.

2. This application contain claims directed to more than one species of the generic Inventions I-IV.
In addition to electing a Group from Inventions I-XVI, applicant must elect an antigen species from:
A) tumor or cancer,
B) virus,
C) protozoan,
D) bacterium,
E) fungus or
F) toxin.

These species are distinct because the targets address differ structures and in turn address different pathological conditions which differ in etiologies and therapeutic endpoints.

It is noted that the recitation of pathogen is not indicated above, as it appears that the listing of (A)-(E) read on pathogen.

In addition, if applicant elects tumor or cancer antigen, then applicant is required to elect a tumor or cancer antigen from:

A) prostate,
B) breast,
C) ovarian,
D) lung,
E) head or neck,
F) uterine,
G) leukemia,
H) skin
I) bladder or
J) melanoma.

These cancer antigens are distinct because their structures and modes of action are different and, in turn, address different endpoints.

If applicant elects a viral antigen, then applicant is required to elect a viral antigen from:

A) papilloma virus,
B) RSV,
C) herpes,
D) influenza,
E) hepatitis,
F) polio or
G) HIV.

These viral antigens are distinct because their structures and modes of action are different and, in turn, address different endpoints.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 29, 2003